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Re-evaluation Decision RVD2010-09

Para-dichlorobenzene

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Overview

Re-evaluation Decision

After a re-evaluation of the insecticide para-dichlorobenzene, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing para-dichlorobenzene for sale and use in Canada.

An evaluation of available scientific information found that products containing para-dichlorobenzene do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of para-dichlorobenzene uses, new risk-reduction measures must be implemented for all products. Additional data are requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of para-dichlorobenzene was first presented in Proposed Re-evaluation Decision document PRVD2010-07, *Para-dichlorobenzene*, a consultation document[1]. This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of para-dichlorobenzene as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-07. To comply with this decision, registrants of products containing para-dichlorobenzene will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

Para-dichlorobenzene as a pest control product is part of the PMRA's current pesticide re-evaluation program. This program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities.

Para-dichlorobenzene is also used as a deodorant, and has been assessed under the *Canadian Environmental Protection Act* (CEPA) in 1993 and 2003.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

In the US, pesticide uses of para-dichlorobenzene have undergone re-evaluation as part of the Environmental Protection Agency Program, and a Reregistration Eligibility Decision (RED) document was published in December 2008. Based on the health and environmental risk assessments published in the 2008 RED, the USEPA concluded that para-dichlorobenzene was eligible for registration provided risk-reduction measures were adopted. The USEPA RED was found to cover the science areas that are necessary for the Canadian re-evaluation of para-dichlorobenzene pest control uses, and to address all formulation types and uses of para-dichlorobenzene in Canada.

The USEPA RED and the Canadian CEPA assessments were used as a basis for the proposed Canadian re-evaluation decision.

In this decision, the PMRA has also taken into consideration the Canadian specific chemistry of registered pest control products as well as the federal Toxic Substances Management Policy (TSMP).

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-07, *Para-dichlorobenzene*.

What Is Para-dichlorobenzene?

Para-dichlorobenzene is an insecticide used to control moth and moth larvae which are destructive to textiles made of natural fibres. Mothballs are placed by hand by home owners in chest boxes or airtight trunks where clothing is stored.

Health Considerations

Can Approved Uses of Para-dichlorobenzene Affect Human Health?

Para-dichlorobenzene is unlikely to affect your health when used according to the revised label directions.

Exposure to para-dichlorobenzene could occur during placement of mothballs by home owners, after placement from inhabiting indoor treated areas with para-dichlorobenzene, and from accidental ingestion of mothballs by children.

The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

The 2008 USEPA RED covers the aspects of human health risk assessment that are necessary for the Canadian re-evaluation of pesticide uses of para-dichlorobenzene, and it addresses all para-dichlorobenzene formulation types and uses registered in Canada. The USEPA concluded that para-dichlorobenzene was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

The CEPA assessment estimated the potential risk to the Canadian population from exposure to para-dichlorobenzene based on measured concentrations in homes in Canada. Although this assessment cannot be directly related to the use of pest control products since there are multiple sources of para-dichlorobenzene, the overall conclusion was taken into consideration in this re-evaluation. The CEPA assessment has concluded that para-dichlorobenzene is not entering the environment in quantities or under conditions that may constitute a danger in Canada to human life or health. No additional mitigation measures were proposed.

The PMRA concluded that para-dichlorobenzene was unlikely to affect human health provided that risk-reduction measures were implemented.

Environmental Considerations

What Happens When Para-dichlorobenzene Is Introduced Into the Environment?

Para-dichlorobenzene is unlikely to affect non-target organisms when used according to the revised label directions.

According to label directions, mothballs are to be placed exclusively indoors and no environmental exposure is expected to result from the use of para-dichlorobenzene as a pest control product. Furthermore, the 2003 CEPA assessment concluded that para-dichlorobenzene is not entering the environment in quantities or under conditions that may be harmful to the environment.

Measures to Minimize Risk

As a result of the re-evaluation of para-dichlorobenzene, the PMRA is proposing further risk-reduction measures.

- Modification of packaging to reduce the potential for accidental ingestion by toddlers.
- Add the statement: "For indoor use only" to clarify that outdoor uses are not permitted.
- Add the statement: "Do not place in areas accessible to children".

Appendix I lists all required mitigation measures.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix II lists all data requirements.

Other Information

Any person may file a notice of objection[3] regarding this decision on para-dichlorobenzene within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Additional Mitigation Measures Required for Products Containing Para-Dichlorobenzene

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The end-use products in Canada must be amended to further protect workers and the environment.

1) Packaging amendments:

Registrants are required to modify the packaging of end-use products to mitigate the risk of accidental ingestion of mothballs by children. Loose mothballs should no longer be sold in Canada, and registrants are required to submit a proposal for packaging/formulation options which would discourage children from eating the product (for example, para-dichlorobenzene formulated as blocks or cakes, packaged individually in sachets). Additional label language is also required to ensure that para-dichlorobenzene products are not applied to areas accessible to children. Registrants are required to modify the packaging of mothballs and flakes to minimize the release of vapours while para-dichlorobenzene products are in storage. Submission of a proposal for packaging options is required; this may include use of a re-sealable hermetically closed container, and reduction of the number of mothballs/amount of flakes per product.

2) Label amendments

The following statement must be added to the **PRIMARY DISPLAY PANEL**

For indoor use only.

The following statement must be added in a section entitled **DIRECTIONS FOR USE**.

Do not place in areas accessible to children.

Appendix II Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of end-use products of para-dichlorobenzene are required to provide these data within the timeline specified in the decision letter that will be sent by the PMRA.

DACO 2.11.3 Detailed Production Process Description

Detailed information on the manufacturing process of the technical grade active ingredient product must be provided.

DACO 2.13.4 Impurities of Toxicological Concern

Recent analytical data from at least five recent batches of the technical grade active ingredient product must be provided for tetrachlorobenzene, pentachlorobenzene and hexachlorobenzene, from a good laboratory practice (GLP)-compliant or government accredited laboratory. The analytical method(s) used must utilize the lowest practical limits of quantitation and fully specified, either by reference to a standard method or by inclusion of a detailed description together with validation data.